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09/764,163	01/16/2001	Robert F. Balint	PARE.002.02US	7613

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EXAMINER

GROSS, CHRISTOPHER M

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1639

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/764,163	<b>Applicant(s)</b> BALINT ET AL.	
	<b>Examiner</b> Christopher M. Gross	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 80,84,85,87,88 and 90-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 80,84,85,87,88 and 90-97 is/are rejected.
- 7) ☒ Claim(s) 87 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Responsive to communications entered 4/16/2007 Claims 80,84-85,87-88,90-97 are pending. Claims 80,84-85,87-88,90-97 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) [taken from MPEP 201.01]

This application filed 1/16/2001 claims benefit of 60/175,968 filed 01/13/2000 and is a CIP of 09/526,106 filed 03/15/2000 (now ABN). It is noted, however, support for: "scaffold peptides" as interactor domains (claims 80,93); the N-terminal break-point and C-terminal break-point are within 10 amino acids in either direction from a junction of 2 amino acid residues located between alpha-helices 7 and 8 (claim 80); the ligand is an antigen-second monomer of heterodimerizing helix fusion protein & the ligand is a

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antibody-second monomer of heterodimerizing helix fusion protein (claim 90); the ligand is an antigen-fos helix fusion protein (claim 94); the ligand is a fos helix-antigen fusion protein (claim 95); the ligand is a scFv antibody-fos helix fusion protein (claim 96); the ligand is a scFv antibody-jun helix fusion protein (claim 97) are not disclosed in the earlier applications. See also 35 USC 112 first and second paragraph considerations below.

Therefore 1/16/2001 is the date for the purposes of prior art concerning claims 80,84-85,87-88,90-97.

***Withdrawn Objection(s) and/or Rejection(s)***

The objection to claim 84 because of break point was spelled out as two words is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of Claims 80 and 84-88 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is hereby withdrawn in view of applicant's amendments to the claims.

The provisional rejection of claims 80, 84-88 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 63-74 of copending Application No. 10/668,778 is hereby withdrawn in view of applicant's arguments.

***Maintained Claim Rejection(s) - 35 USC § 112***

Claims 80,85-86,88, 90-97 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for circularly permuted beta-lactamase comprising N and C interactor domains with a breakpoint between Glu197 and Leu198

it, does not reasonably provide enablement for the other breakpoints set forth in claim 80.

Please note that the above rejection has been modified from the original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

*Response to Arguments*

Applicant argues, see IFW p 5-6 (4/16/2007), that the amendment to claim 80, directed to "wherein [the] N-terminal break-point and C-terminal break-point are within 10 amino acids in either direction from a junction of 2 amino acid residues located between alpha-helices 7 and 8" encompasses the enabled break-point between residues Glu 197 and Leu 198 of beta lactamase. It is noted, however, that alpha-helix 7 begins at Thr-200 and alpha helix 8 ends at His-289, thus the enabled break-point lies *outside* of the claimed range. Introduction of a break-points between Leu-190 and Trp-290 would entail undue experimentation, as detailed in the last Office Action. See also 35 USC 112 second paragraph considerations below.

***Maintained Claim Rejection(s) - 35 USC § 102***

Claims 80, 84, 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Pieper et al (1997 Biochemistry 36:8767 – IDS entry 5/5/2004).

Please note that the above rejection has been modified from the original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

*Response to Arguments*

Applicant argues not all elements are taught.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

Specifically, applicant argues see IFW p 5-6 (4/16/2007), Pieper et al do not teach first and second interactor domains fused through the claimed N and C break-point. In this regard it is noted that according to claim 80, the interactor domains may represent "scaffold peptides." Giving the claims the broadest reasonable interpretation, it is noted that *all* proteins, including circularly permuted varieties, such as the beta lactamase set forth by Pieper et al comprise a peptide scaffolds fused at their respective N and C termini.

Applicant further argues, see IFW p 6 (4/16/2007), that Pieper et al do not teach introduction of a break-point between helices 7 and 8, however it is noted that alpha helix 7 in beta lactamase runs from Thr-200 through Ala-213, whereas alpha helix 8 runs from Thr-271 through His-289. The break-point according to Pieper is positioned between either of Gly-253 and Lys-254 or Ala-227 and Gly-228, both of which are between the beginning of alpha helix 7 and end of alpha helix 8. See also 35 USC 112 1<sup>st</sup> and 2<sup>nd</sup> paragraph considerations below)

Additionally, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., break-point(s) between Thr-195 to Ala-202) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification,

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limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

***New Claim Rejections - 35 USC § 112***

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 80,84-85,87-88,90-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*This rejection is necessitated by applicant's amendments to the claims.*

Claim 80 recites the limitation: "wherein [the] N-terminal break-point and C-terminal break-point are within 10 amino acids in either direction from a junction of 2 amino acid residues located between alpha-helices 7 and 8," which is considered vague and indefinite for the following reasons.

Evidence provided by the protein data bank (PDB) entry concerning the secondary structure of beta lactamase indicates alpha helix 7 runs from Thr-200 through Ala-213, whereas alpha helix 8 runs from Thr-271 through His-289.

It is noted 10 amino acids before Thr-200, (i.e. Leu 190) is in the middle of alpha helix 6, which is not considered between the beginning of alpha-helix 7 and the end of alpha helix 8. 10 residues after His-289 does not exist because Trp 290 represents the C terminus (i.e. last residue) of beta lactamase.

Due to the above ambiguity, the metes and bounds of the claimed break-point are rendered unascertainable. It is further noted that claimed range (from Leu-190 through Trp-290) is outside of the enabled breakpoint at Glu-197/Leu-198 per claim 87.

### ***Claim Objections***

Claim 87 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 87 moves the claimed break-point range set forth in claim 80, from between helix 7 and 8 plus or minus 10 residues (i.e. between residues Leu-190 and Trp 290) to a break-point position at Glu-197/Leu-198, which is outside of said range.

*This objection is necessitated by applicant's amendments to the claims.*

### ***New Claim Rejection(s) – 35 USC § 112***

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 80,84-85,87-88,90-97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states



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that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

*This rejection is necessitated by Applicant's amendment to the claims.*

Claims 80 and 93 has inserted limitations directed to "scaffold peptides" as interactor domains and the N-terminal break-point and C-terminal break-point are within 10 amino acids in either direction from a junction of 2 amino acid residues located between alpha-helices 7 and 8.

Claim 90 has introduced various ligands including: an antigen-second monomer of heterodimerizing helix fusion protein; a second monomer of hetero-dimerizing helix-antigen fusion protein; an antibody-second monomer of heterodimerizing helix fusion protein

Claims 94-97 has introduced various ligands including: an antigen-fos helix fusion protein (claim 94); a fos helix-antigen fusion protein (claim 95); a scFv antibody-fos helix fusion protein (claim 96); a scFv antibody-jun helix fusion protein (claim 97). The ligands set forth in claims 94-97 are taken as including free ligands (separate from the beta lactamase construct).

The specification as originally filed provided no implicit or explicit support for: scaffold peptides; a break-point between Leu-190 and Trp-290 (i.e. a break-point are within 10 amino acids in either direction from a junction of 2 amino acid residues located between alpha-helices 7 and 8); and free ligands as fusion proteins.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the claims. See 37 CFR 1.121 (b)(2)(iii), the MPEP 714.02, 3<sup>rd</sup> paragraph, last sentence and also the MPEP 2163.07, last sentence.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross  
Examiner  
Art Unit 1639

cg

/Jon D. Epperson/  
Primary Examiner, AU 1639